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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,271	03/30/2001	Michael A. Faltys	AB-131U	7283

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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application

09/823,271

Applicant(s)

FALTYS ET AL.

Examiner

Kristen L Droesch

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 23-26 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-32 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-18 is/are rejected.
- 7) ☒ Claim(s) 5,6 and 19-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-22, 27-32, drawn to an implantable tissue stimulation prosthesis, classified in class 607, subclass 57.
 - II. Claims 23-26, drawn to an electrode array, classified in class 607, subclass 115.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not include at least four banks of active electrodes including a plurality of active electrodes where each active electrode has a plurality of contacts and circuit means adjacent the contacts for individually activating the electrode contacts. The subcombination has separate utility such as spinal stimulation lead.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Bryant Gold on 4/2/03 a provisional election was made without traverse to prosecute the invention of Group I, claim 1-22, 27-32.

Art Unit: 3762

5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

6. Claim 2 is objected to because of the following informalities: “. . . circuitry hermetically sealed in said sealed case.” The examiner suggests changing the clause to --. . . circuitry in said hermetically sealed case.-- Appropriate correction is required.

7. Claim 10 is objected to because of the following informalities: “. . . applied through selected groupings of the plurality of individual electrodes are applied through selected electrode groupings . . .” Appropriate correction is required.

8. Claim 18 is objected to because of the following informalities: “. . . plurality of individual electrodes included within each active electrode comprises. . .” The examiner suggests substituting --contacts-- for “electrodes”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Loeb et al. (5,649,970). Loeb et al shows an implantable tissue stimulation prosthesis comprising an implantable hermetically sealed case (Fig. 8, Col. 11, lines 19-23); an active electrode array (Figs. 5-7), comprising a plurality of active electrodes wherein each active electrode includes

Art Unit: 3762

switching circuitry (56) and a plurality of individual electrode contacts (14, 20) that may be individually activated by electrode control signals applied to the switching circuitry; a battery (52) carried within the sealed case; electronic circuitry (50) housed within the sealed case including telemetry circuitry (44) that receives programming signals from an external source, the electronic circuitry also includes circuitry for generating electrode control signals and generating stimulation currents applied through selected ones of the plurality of individual electrodes (Col. 8, lines 21-29; Col. 8, line 52-Col. 9, line 7; Col. 11, line 48-Col. 12, line 12; Col. 13, lines 32-43, Fig. 8).

With respect to claim 17, Loeb et al. shows the active electrode array comprises at least four active electrodes (Figs. 5-7).

Regarding claim 18, Loeb et al. shows the plurality of individual electrodes within each active electrode comprises at least one lateral electrode (14) and one medial electrode (20).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb et al (5,649,970) in view of Muller (5,814,095). Loeb et al. shows a fully implantable tissue stimulation prosthesis comprising an implantable hermetically sealed case (Fig. 8, Col. 11, lines 19-23); an active electrode array (Figs. 5-7), comprising at least one electrode group and associated switching circuitry (56), wherein the at least one electrode group includes a plurality

Art Unit: 3762

of individual electrodes that may be individually activated by electrode control signals applied to the switching circuitry; electronic circuitry (50) housed within the sealed case for receiving and processing signals, for generating electrode control signals and generating stimulation currents applied through selected groupings of the plurality of individual electrodes (Col. 8, lines 21-29; Col. 8, line 52-Col. 9, line 7; Col. 11, line 59-Col. 12, line 12; Col. 13, lines 32-43). Although Loeb et al. fails to specifically show an implantable microphone or battery carried within the sealed case, attention is drawn to Muller who shows an implantable tissue stimulation prosthesis including an implantable microphone (5, 11) and a battery within the sealed case (B). Muller teaches that utilizing an implantable cochlear prosthesis with an implantable microphone and battery allows patients to avoid the disability and stigmatization caused by the use of a conventional cochlear prosthesis which requires the speech processor, and microphone to be worn outside the body (Col. 2, lines 19-39). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the Loeb et al. device with the implantable microphone and battery of Muller in order to avoid patient disability and stigmatization.

13. Claims 2-4, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb et al (5,649,970) in view of Muller (5,814,095) as applied to claim 1 above, and further in view of Kuzma (5,105,811). Loeb et al. and Muller are as explained before. Although Loeb et al. and Muller fail to show the electrode array is detachably connected to the electronic circuitry in the hermetically sealed case, attention is directed to Kuzma who teaches it is necessary to be able to disconnect the electronic circuitry in the hermetically sealed case from the electrode array to enable replacement with another sealed case (Col. 1, line 56-Col. 2, line 7). Therefore it

Art Unit: 3762

would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the Loeb et al. and Muller device with the detachable electrode array/ sealed case of Kuzma in order to enable replacement with another sealed case and associated electronic circuitry.

Regarding claim 3, Loeb et al shows the at least one electrode group comprises at least one lateral electrode contact (14) and at least one medial electrode contact (20).

With respect to claim 4, Loeb et al. shows the lateral and medial contacts electrically connect with the switching circuitry (56) and the switching circuitry responds to electrode control signals to selectively activate one or both of the medial or lateral electrode contacts (Col. 11, line 59-Col. 12, line12).

Regarding claims 8-9, Loeb et al. and Muller both show the prosthesis includes a coil for receiving and sending signals to and from the circuitry within the sealed case and the signals received through the coil provide operating power to recharge the battery (B, 52) housed within the sealed case ('095 – Col. 11, lines 11-34; '970 – Col. 11, lines 48-58). Although the frequency of the signal is not specifically mentioned, it is inherent that the frequency of the signals is RF.

With respect to claim 10, Loeb et al. shows the active electrode array is adapted for insertion into a human cochlea and the stimulation currents are applied through selected groupings of the individual electrodes in order to provide hearing sensation.

14. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb et al (5,649,970) in view of Muller (5,814,095) as applied to claim 1 above, and further in view of Soykan et al. (6,236,889). Loeb et al. and Muller are as explained before. Although Loeb et al.

Art Unit: 3762

and Muller fail to show means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone, attention is directed to Soykan et al. Soykan shows an implantable device with a microphone and means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone (Col. 2, lines 32-42; Col. 3, line 67-Col. 4, line 4; Col. 10, lines 59-62; Col. 13, lines 5-13). Soykan et al. teaches that the means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone provides a low cost, less complex telemetry system compared to conventional electromagnetic telemetry techniques and allows increased freedom of patient movement (Col. 1, lines 16-52; Col. 12, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the Loeb et al. and Muller device with the means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone taught by Soykan et al. since it provides a low cost, less complex telemetry system compared to conventional electromagnetic telemetry techniques and allows increased freedom of patient movement.

Regarding claim 12, Soykan et al shows the acoustic control signals comprise phase-shift keyed modulation within a narrow frequency band (Col. 9, line 56- Col. 10, line 7).

15. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb et al (5,649,970) in view of Muller (5,814,095) and Soykan et al. (6,236,889) as applied to claim 12 above. Loeb et al., Muller and Soykan et al. are as explained before. Loeb et al., Muller and Soykan et al. disclose the claimed invention except for the narrow frequency band centered at 6KHz. It would have been an obvious design choice to one with ordinary skill in the art at the

Art Unit: 3762

time the invention was made to modify the center of the narrow frequency band as taught by Soykan et al. with 6 KHz, since applicant has not disclosed that this particular center of the narrow frequency band provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any center of a narrow frequency band such as the 600 Hz, 1200 Hz or 2400 Hz taught by Soykan et al. for acoustic data transmission.

16. Claims 1, 7, and 14-15 are rejected under 35 U.S.C. 103(a) as being obvious over Faltys et al. (6,289,247) in view of Muller (5,814,095). Faltys et al. shows a fully implantable tissue stimulation prosthesis comprising an implantable hermetically sealed case (21) an active electrode array (48, Fig. 8), comprising at least one electrode group and associated switching circuitry wherein the at least one electrode group includes a plurality of individual electrodes (M1-M8, L1-L8) that may be individually activated by electrode control signals applied to the switching circuitry; electronic circuitry housed within the sealed case for receiving and processing signals, for generating electrode control signals and generating stimulation currents applied through selected groupings of the plurality of individual electrodes (Col. 9, lines 16-21, 39-41, 46-54; Fig. 3A) Although Faltys et al. fails to specifically show an implantable microphone or battery carried within the sealed case, attention is directed to Muller who shows an implantable tissue stimulation prosthesis including an implantable microphone (5, 11) and a battery within the sealed case (B). Muller teaches that utilizing an implantable cochlear prosthesis with an implantable microphone and battery allows patients to avoid the disability and stigmatization caused by the use of a conventional cochlear prosthesis which requires the speech processor, and microphone to be worn outside the body (Col. 2, lines 19-39). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made

Art Unit: 3762

to modify the Faltys et al. device with the implantable microphone and battery of Muller in order to avoid patient disability and stigmatization.

With respect to claim 7, Faltys et al shows the electronic circuitry enclosed within the sealed case includes both digital and analog circuitry (18, 52, Fig. 3A).

Regarding claim 14, Faltys et al. shows means for determining a simultaneous N of M strategy (Col. 13, line 63-Col. 14, line 8).

With respect to claim 15, Faltys et al shows the electronic circuitry further includes a plurality of pulse generator circuits and means for defining a pulse table (42) that drives the generator circuits (Col. 15, lines 24-40).

17. Claims 2-4, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys et al. (6,289,247) in view of Muller (5,814,095) as applied to claim 1 above, and further in view of Kuzma (5,105,811). Faltys et al. and Muller are as explained before. Although Faltys et al. and Muller fail to show the electrode array is detachably connected to the electronic circuitry in the hermetically sealed case, attention is directed to Kuzma who teaches it is necessary to be able to disconnect the electronic circuitry in the hermetically sealed case from the electrode array to enable replacement with another sealed case (Col. 1, line 56-Col. 2, line 7). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the Faltys et al. and Muller device with the detachable electrode array/ sealed case of Kuzma in order to enable replacement with another sealed case and associated electronic circuitry.

Regarding claim 3, Faltys et al. shows the at least one electrode group comprises at least one lateral electrode contact (L1-L8) and at least one medial electrode contact (M1-M8 (Fig. 8).

With respect to claim 4, Faltys et al. shows the lateral and medial contacts electrically connect with the switching circuitry and the switching circuitry responds to electrode control signals to selectively activate one or both of the medial or lateral electrode contacts (Col. 9, lines 16-21, 39-41, 46-54; Fig. 3A).

Regarding claims 8-9, Faltys et al. and Muller both show the prosthesis includes a coil for receiving and sending signals to and from the circuitry within the sealed case and the signals received through the coil provide operating power to recharge the battery (B, 52) housed within the sealed case ('095 – Col. 11, lines 11-34; '247 – Col. 28-39). Although the frequency of the signal is not specifically mentioned, it is inherent that the frequency of the signals is RF.

With respect to claim 10, Faltys et al. shows the active electrode array is adapted for insertion into a human cochlea and the stimulation currents are applied through selected groupings of the individual electrodes in order to provide hearing sensation.

18. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys et al. (6,289,247) in view of Muller (5,814,095) as applied to claim 1 above, and further in view of Soykan et al. (6,236,889). Faltys et al. and Muller are as explained before. Although Faltys et al. and Muller fail to show means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone, attention is directed to Soykan et al. Soykan shows an implantable device with a microphone and means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone (Col. 2, lines 32-42; Col. 3, line 67-Col. 4, line 4; Col. 10, lines 59-62; Col. 13, lines 5-13). Soykan et al. teaches that the means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the

Art Unit: 3762

microphone provides a low cost, less complex telemetry system compared to conventional electromagnetic telemetry techniques and allows increased freedom of patient movement (Col. 1, lines 16-52; Col. 12, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the Faltys et al. and Muller device with the means for adjusting operating parameters of the electronic circuitry through acoustic remote control signals received through the microphone taught by Soykan et al. since it provides a low cost, less complex telemetry system compared to conventional electromagnetic telemetry techniques and allows increased freedom of patient movement.

Regarding claim 12, Soykan et al shows the acoustic control signals comprise phase-shift keyed modulation within a narrow frequency band (Col. 9, line 56- Col. 10, line7).

19. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys et al (5,649,970) in view of Muller (5,814,095) and Soykan et al. (6,236,889) as applied to claim12 above. Faltys et al., Muller and Soykan et al. are as explained before. Faltys et al., Muller and Soykan et al. disclose the claimed invention except for the narrow frequency band centered at 6KHz. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the center of the narrow frequency band as taught by Soykan et al. with 6 KHz, since applicant has not disclosed that this particular center of the narrow frequency band provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any center of a narrow frequency band such as the 600 Hz, 1200 Hz or 2400 Hz taught by Soykan et al. for acoustic data transmission.

20. The applied Faltys et al. reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only

Art Unit: 3762

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Allowable Subject Matter

21. Claims 5-6, and 19-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 5-6, the prior art of record fails to teach or suggest switching circuitry and lateral and medial electrode contacts formed on a silicon die and a plurality of the silicon dies are stacked and over-molded with silastic to form the active electrode array in combination with the remaining elements of the claims.

Art Unit: 3762

With respect to claims 19-22, the prior art of record fails to teach or suggest switching circuitry of each active electrode comprises decoding circuitry, a first switch coupled to the decoding circuitry and the at least one lateral electrode contact and a second switch coupled to the decoding circuitry and the at least one medial electrode contact in combination with the remaining elements of the claims.

22. Claims 27-32 are allowed. The prior art of record fails to teach or suggest a fully implantable cochlear prosthesis comprising an implantable sealed case with electronic circuitry, a battery and a microphone housed within, an active electrode array detachably connected to the electronic circuitry within the case by a connector, in combination with the active electrode array including a programmable number of both medial and lateral electrode contacts, and active switching elements included within the array through which any one of the contacts may be selected to apply stimulation current.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pohndorf et al (4,628,934) shows a plurality of electrodes that are selectively activated using switching circuitry. Peeters et al. (6,355,064), van den Honert et al. (5,000,194), Loeb (5,833,714) each show cochlear implants having lateral and medial electrodes.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 8:00 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the

Art Unit: 3762

organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Krista Droschel

kld
April 5, 2003

Kennedy Schaeetzle
KENNEDY SCHAETZLE
PRIMARY EXAMINER
4-7-03